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(54) Prevention of anal leakage of polyorganosiloxane fluids used as fat substitutes in foods.

(57) What is disclosed are food compositions which contain a polyorganosiloxane fluid as a fat substitute and an anti-anal leakage agent. The anti-anal leakage agents comprise C_{12}-C_{24} essentially saturated fatty acids or edible, digestible sources thereof; non-degradable, water insoluble fibers of plant origin and silica.

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PREVENTION OF ANAL LEAKAGE OF POLYORGANOSILOXANE FLUIDS USED AS FAT SUBSTITUTES IN FOODS

The present invention relates to a method of controlling the anal leakage of polyorganosiloxane fluids used as fat substitutes in food by adding an anti-anal leakage agent of the type disclosed hereinafter to the liquid siloxane or to foods containing same.

Non-degradable polyorganosiloxane fluids can be substituted for fats in food compositions. However, rats fed a diet containing about 6.5% by weight of polyorganosiloxane fluid exhibited undesirable anal leakage of the siloxane fluid. It has now been determined that this undesirable affect can be obviated by combining the polyorganosiloxane fluid with certain anti-anal leakage (AAL) agents. The types of AAL agents which can be used to overcome the above-described anal leakage problem are disclosed herein.

For purposes of this invention, the silicones can be described as polyorganosiloxanes which have an organic carbon content of at least fifteen (15) weight percent. Included within the scope of this invention are those siloxanes having organic substitutions wherein the organic substitution is linked to the silicon atom through a carbon/silicon bond. Such a limitation distinguishes the siloxanes useful in this invention from those wherein there is no organic substitution such as partial hydrolyzates and condensates of $Si(OR)_4$ wherein R is an alkyl radical. Further, this invention contemplates small amounts of -Si-O-C- bonded materials wherein the hydrolyzable by-products of such materials are not toxic to the human body, such as for example, ethanol, glycerol, sucrose and other organic sugars.

In order to minimize the possibility of absorption of the siloxanes in the gastrointestinal tract, the siloxanes preferred for this invention should not contain significant amounts of material with molecular weights of less than 500 g/mole. By "significant", it is meant that there should be less than about 10 weight percent of such low molecular weights materials present in the composition, based on the total siloxane present. Preferred for this invention are siloxanes that are essentially free of low molecular weight materials as defined.

Also, preferred for this invention is a polyorganosiloxane fluid of the general formula $(CH_3)_3SiO[(CH_3)_2SiO]_bSi(CH_3)_3$ wherein b has an average value of 25 to 500.

The siloxanes of this invention need not necessarily be truly soluble or miscible with the other components of the foods in which they are being used. They may be combined with the food either separately or in combination with the anti-anal leakage agent.

The polyorganosiloxane fluid may be substituted in the food in a quantity of about 0.1 to 100 percent of the total food composition. The amount of siloxane used will depend on the amount of fat in the food composition.

Types of food compositions within the scope of this invention include salad oils and salad dressings; dairy products such as cheese, cottage cheese, milk, ice cream, whipped cream and yogurt; baked goods such as cakes, pie crusts, cookies, bread, cereal, doughnuts and crackers; shortening substitutes; margarine; mayonnaise; peanut butter; and other food compositions where the fat component can be substituted with silicone oil.

One class of materials which provide the AAL effect herein includes fatty acids having a melting point of ca. 37° C. or higher and ingestible, digestible sources of such fatty acids. The fatty acid AAL agents include, for example, the C_{12}-C_{24} saturated fatty acids and ingestible, digestible sources thereof.

Non-limiting examples of saturated fatty acids and sources thereof which can be used as the AAL agent herein include the free saturated fatty acids **per se**, compounds such as esters (e.g. triglycerides) that yield such saturated fatty acids on hydrolysis in the gut, soaps of the fatty acids such as the sodium, potassium, water-soluble soaps, as well as the calcium and magnesium water-soluble soaps.

Highly preferred herein for their anti-anal leakage effect are the C_{16}-C_{22}, most preferably C_{16}-C_{18}, saturated fatty acids or edible sources thereof.

Specific examples of materials useful as the foregoing type of AAL agent herein include C_{16}-C_{22} saturated fatty acids such as stearic acid, natural or processed fats yielding C_{12}-C_{24} saturated fatty acids in the gut, e.g. materials such as cocoa butter, palm oil, palm kernel oil, coconut oil, tallow, lard, suet, enriched concentrates of triglycerides having high levels of saturated fatty acids obtainable from these sources and sources such as highly saturated cottonseed oil fractions obtained by processes such as crystallization or directed rearrangement which yield the desired higher concentrations of the more saturated fatty acids in the resulting "hardstock" fractions.

Partially hydrogenated oils including all of the above, as well as partially hydrogenated soybean oil, safflower seed oil, rapeseed oil or such materials which are hydrogenated and concentrated, for example by crystallization, to provide fractions which are enriched in sources of the longer-chain,

substantially saturated fatty acids, are all useful as the AAL agent herein. (By "substantially hydrogenated" herein is meant oils having an iodine value of ca. 50 or lower.) Any of the foregoing unsaturated oils are useful herein after they have been substantially completely hydrogenated to convert the unsaturated fatty acid (ester) groups to the corresponding saturated fatty acids.

A second class of materials which provided the anti-anal leakage effect described herein is particulate silica. To be effective at the concentrations claimed herein the particulate silica should have a surface area of greater than 10 m^2/g as determined by the BET method. The BET method of measuring surface area is based on the adsorption of nitrogen at its boiling point under 1 atm pressure and measures both the interior as well as the total surface area of the particles. For the present invention, it is believed that the exterior surface area of the particle is the critical area. In cases where particles have considerable surface area interior to the particle, it is anticipated one skilled in the art will appropriately adjust the weight of silica used to provide the requisite exterior surface area.

Preferred is a silica with a surface area of at least 80 m^2/g and most preferred is a silica with a surface are of about 300 m^2/g to about 400 m^2/g.

The silica particles used as the AAL agent may be produced by any process adequate to produce the required surface area including grinding, milling, precipitation and vapor phase deposition.

A third class of materials which provided the anti-anal leakage effect described herein is edible, non-degradable, water insoluble fibers of plant origin. By edible is meant those fibers which are palatable or can be rendered palatable by treatment or appropriate formulation. In addition, edibility implies the fibers, associated constituents and degradation products thereof are to be essentially non-toxic when ingested at the levels contemplated in this invention. Non-degradable refers to the ability to pass through the gastrointestinal tract essentially unchanged by normal digestive and bacterial processes. Water insoluble fibers of plant origin includes those fibers comprising cellulose, hemicellulose and lignin in combination or isolates thereof.

A preferred embodiment of this class of anti-anal leakage agents is bran. Bran is a natural source of fiber consisting essentially of the water insoluble coats of seeds of legumes and cereals. Legumes refer to the seeds and fruits of dicotyledonous plants such as beans, peas, clover and alfalfa. Cereal relates to a plant yielding farinaceous grain suitable for food such as corn, wheat, oat, rye, barley and rice. Farinaceous refers to grains rich in starch.

Also, included within the scope of this invention are isolates comprising cellulose, hemicellulose and lignin separately or in combination. Fiber from plant sources other than those specified are also useful as anti-anal leakage agents.

Preferred AAL agents of this invention include cellulose, hemicellulose and lignin fibers or sources thereof with an average mean particle size of less than about 36 microns. Such AAL agents with an average mean particle size of less than about 28 microns are more preferred. Another preferred AAL agent of this invention is the bran flour of cereal grains which 100% passes a USS 40 mesh screen and 90% is retained by a USS 120 mesh screen.

The AAL agent may be incorporated into the food composition either separately or by first being combined with the siloxane fluid. The AAL agent and fluid in combination or individually may be added to the food as appropriate during formulation, processing or preparation. It is preferred that the AAL agent be present in the final food composition at a concentration of at least about 10% by weight of the combined siloxane and AAL agent portions of the food composition. It is more preferred that the AAL agent be present in the final food composition at a concentration of at least about 20% by weight of the combined siloxane and AAL agent portions of the food composition. It is most preferred that the AAL agent is present at a concentration of about 20% to about 50% by weight of the combined siloxane and AAL agent portions of the food composition. These concentrations as specified reduce or abolish anal leakage of the siloxane fluid.

Those skilled in the art will recognize that the disclosed AAL agents if found normally in a food may allow adjustment of the actual AAL agent required to be added to the food. In addition, it may be recognized that diets containing the disclosed AAL agents could reduce the amount of AAL agent needed in a food composition to prevent anal leakage. The concentrations presented in the food compositions of this invention are those which reduce or prevent anal-leakage in the absence of other potential sources of AAL agent activity.

The following non-limiting examples illustrate the composition of this invention.

Example 1

As a control food composition a polyorganosiloxane fluid of the general formula $(CH_3)_3SiO[(CH_3)_2SiO]_bSi(CH_3)_3$ wherein b had an average value of about 35 was blended into Purina Rat Chow 5012 Meal (Ralston Purina Company, St. Louis, Missouri) in the proportions of: 1500 g rat chow + 105 g siloxane fluid. A group of five adult rats weighting 275-350 g was allowed ad libitum access to this food composition as their exclusive

diet for seven days. Animals were observed daily for evidence of anal leakage. Within 48 hours of access to this diet, all animals demonstrated slight to moderate anal leakage of the siloxane fluid.

Example 2

Stearic acid, as representative of the group of C_{12}-C_{24} saturated fatty acids, was incorporated as an AAL agent into the food composition of Example 1 in the following proportions: 1500 g rat chow + 105 g siloxane fluid + 30 g stearic acid. Other experimental details were the same as those specified in Example 1. None of the five animals fed this diet with stearic acid added as an AAL agent demonstrated signs of anal leakage of the siloxane fluid at any time during the seven day observation period.

Example 3

Suet is representative of naturally occurring digestible fats which can serve as a source for C_{12}-C_{24} saturated fatty acids and their esters. In this example, the food composition of Example 1 was blended with suet as an AAL agent in the following proportions: 1500 g rat chow + 105 g siloxane fluid + 30 g suet. Other experimental details where the same as in Example 1. None of the five animals fed this diet with suet added as an AAL agent demonstrated signs of anal leakage of the siloxane fluid at any time during the seven day observation period.

Example 4

To the food composition of Example 1 was added silica with an average surface area of about 300 m^2/g to about 400 m^2/g in the proportions of 1500 g rat chow + 105 g siloxane fluid + "n" g silica wherein n was 1, 3, 7, 15 or 30 g. Other experimental details where the same as in Example 1. A separate group of five animals each was used for each food composition tested. All test groups displayed a reduction in the incidence and severity of anal leakage in relation to the control group of Example 1. In general, as more silica was added to the diet the time to appearance of anal leakage increased and the number of animals displaying anal leakage decreased. Only the test group receiving the diet containing 30 g of silica was free of all signs of anal leakage of siloxane fluid.

Example 5

To the food composition of Example 1 was added silica with a particle size of 32-63 micrometer in the proportions of: 1500 g rat chow + 105 g siloxane fluid + 30 g silica. Other experimental details were the same as given in Example 1. Silica of this particle size at the concentration tested effected a reduction in the severity and incidence of anal leakage of siloxane fluid in relation to the control group of Example 1. However, complete abatement of the anal leakage in all animals of the test group was not achieved.

Example 6

Solka Floc 200 (James River Corporation, Hackensack, NJ) a mechanically ground cellulose of 30-35 micrometer average particle size was added to the food composition of Example 1 in the following proportion: 1500 g rat chow + 105 g siloxane fluid + 30 g of Solka Floc 200. Other experimental details were the same as given in Example 1. Solka Floc 200 at the concentration tested reduced the severity and incidence of anal leakage of siloxane in relation to the control group of Example 1. However, complete abatement of anal leakage in all animals of the test group was not achieved.

Example 7

Solka Floc 300 (James River Corporation, Hackensack, NJ) a mechanically ground cellulose of 22-24 micrometer average particle size was added to the food composition of Example 1 in the following proportions: 1500 g rat chow + 105 g siloxane fluid + 30 g of Solka Floc 300. Other experimental details were the same as those of Example 1. One of five test animals had signs of slight anal leakage of the siloxane fluid at 24 and 48 hours after being placed on the test diet containing Solk Floc 300. At 72 hours after being placed on the test diet and thereafter, none of the test animals had signs of anal leakage.

Example 8

Barley bran, a natural source of plant fibers, was added to the food composition of Example 1 in the following proportion: 1500 g rat chow + 105 g siloxane fluid + 30 g barley bran. The barley bran was purchased from National Grain Products Co., Inc., Minnetonka, MN. The bran was produced from barley after malting and removal of sugar and starch by hot water extraction. The extracted barley was dried by indirect steam, milled and sifted to obtain flour which 100% passed through a USS 40 mesh screen and 90% was retained by a USS 120 mesh screen. Other experimental details were the same as those of Example 1. None of the test animals exhibited signs of anal leakage of the siloxane fluid at any time during the test period.

Claims

1. A low calorie food composition comprising non-fat ingredients and fat ingredients wherein about 0.1% by weight to about 100% by weight of the total fat ingredients have been replaced by a fat substitute comprising:

a. an edible, non-absorbable, non-digestible liquid siloxane polymer of the general formula $(CH_3)_3SiO[(CH_3)_2SiO]_bSi(CH_3)_3$ wherein b has an average value of 25 to 500; and

b. sufficient anti-anal leakage agent to prevent leakage of said liquid siloxane through the anal sphincter.

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EUROPEAN SEARCH REPORT

Application Number

EP 89 31 1234

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int. Cl.5)
A	EP-A-0256607 (UNILEVER) * claims 1, 8 *	1	A23L1/308 A23D9/00
A	EP-A-0205273 (DOW CORNING) * claims *	1	
A	GB-A-2113116 (BRISTOL-MYERS) * claims *	1	
A	US-A-4005195 (R.J.JANDACEK) * claims *	1	
A	US-A-4005196 (R.J.JANDACEK) * claims *	1	
A	US-A-4461782 (M.D.ROBBINS ET AL.) * claims *	1	
A	EP-A-0233856 (PROCTER & GAMBLE) * claims *	1	
A	FOOD TECHNOLOGY. no. 01, 1981, CHICAGO US pages 59 - 67; S.C.SHARMA: "Gums and Hydrocolloids in Oil-Water Emulsions" * the whole document *	1	TECHNICAL FIELDS SEARCHED (Int. Cl.5) A23L A23D

The present search report has been drawn up for all claims

Place of search	Date of completion of the search	Examiner
THE HAGUE	30 OCTOBER 1990	VAN MOER A.M.J.

CATEGORY OF CITED DOCUMENTS

X : particularly relevant if taken alone
Y : particularly relevant if combined with another document of the same category
A : technological background
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E : earlier patent document, but published on, or after the filing date
D : document cited in the application
L : document cited for other reasons

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